



# PCT (0/552050

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference H273150MN1MP	FOR FURTHER ACTI	ON See Notific	cation of Transmittal of International Examination Report (Form PCT/IPEA/416)
International application No.	International filing date (	day/month/year)	Priority date (day/month/year)
PCT/FR2003/003221	29 octobre 2003 (	29.10.2003)	30 octobre 2002 (30.10.2002)
International Patent Classification (IPC) or r A61K 9/00	national classification and I	PC	
Applicant	STATICE S	ANTE	
and is transmitted to the applicant	according to Article 36.		national Preliminary Examining Authority sheet.
This report is also accompa amended and are the basis in 70.16 and Section 607 of the	nied by ANNEXES, i.e., sh for this report and/or sheets le Administrative Instructio	neets of the descript containing rectific ns under the PCT).	ion, claims and/or drawings which have been ations made before this Authority (see Rule
These annexes consist of a			
3. This report contains indications re		is.	
Basis of the repor	·		ļ
II Priority	ot of oninion with regard to	novelty, inventive	step and industrial applicability
III Lack of unity of i		,,	
Personal statement	ent under Article 35(2) with	regard to novelty,	inventive step or industrial applicability;
v 🖂 citations and exp	lanations supporting such s	iatement	
VI Certain documen	ts cited the international application	on	·
Contain shearing	ions on the international app		
VIII L Certain observati		-	
Date of submission of the demand		Date of completion	on of this report
28 mai 2004 (28.0	5.2004)	1	7 March 2005 (17.03.2005)
Name and mailing address of the IPEA/	EP	Authorized office	er -
Facsimile No.		Telephone No.	



International application No.

PCT/FR2003/003221

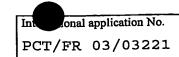
I. Basis of the report							
1. With	regard to	the elements of the international application:*					
	the inte	mational application as originally filed					
$\boxtimes$	the desc	cription:					
	pages	1-19 , as originally filed					
	pages	, filed with the demand					
	pages	, filed with the letter of					
	the clai	ims:					
<u> </u>	pages	, as originally filed					
	pages	, as amended (together with any statement under Article 19					
	pages	, filed with the demand					
	pages	1-11 , filed with the letter of 10 February 2005 (10.02.2005)					
$\boxtimes$	the drav	wings:					
	pages						
	pages	, filed with the demand					
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l 🖂,	the sense	ence listing part of the description:					
~	pages	, as originally filed					
	pages	, as originally filed , filed with the demand					
	pages	, filed with the letter of, and was not defined as					
Thes	the lan the lan the lan the lan or 55.3						
3. With preli	iminary e	to any nucleotide and/or amino acid sequence disclosed in the international application, the international examination was carried out on the basis of the sequence listing:					
		ned in the international application in written form.					
		ogether with the international application in computer readable form.					
		hed subsequently to this Authority in computer readable form					
	ĺ	hed subsequently to this Authority in computer readable form.  Statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the					
		ational application as filed has been furnished.					
	•	tatement that the information recorded in computer readable form is identical to the written sequence listing has furnished.					
4.	The ar	mendments have resulted in the cancellation of:					
		the description, pages					
}	· 🔲	the claims, Nos.					
		the drawings, sheets/fig					
5. 🗌		eport has been established as if (some of) the amendments had not been made, since they have been considered to go d the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**					
in ti	lacement his repor 70.17).	sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to rt as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16					
		ment sheet containing such amendments must be referred to under item 1 and annexed to this report.					

v.	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
	citations and explanations supporting such statement

1. Statement			
Novelty (N)	Claims	1-11	YES
	Claims		NO
Inventive step (IS)	Claims	1-11	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-11	YES
	Claims		NO

#### 2. Citations and explanations

- 1. The documents cited in the search report bear the consecutive numbering D1-D6; said numbering follows the order in which said documents appear in the search report and will be used throughout the rest of the procedure. Except where otherwise specified, the cited passage(s) for each document will be taken into consideration.
- 2. The amendments submitted with the fax dated 10-02-2005 do not appear to cause the subject matter of the application to be extended beyond the content of the application as filed. Consequently, they comply with the provisions of PCT Article 34(2)(b).
- 3. Novelty and inventive step (PCT Article 33(2) and (3))
- 3a. The subject matter of claims 1-5 is novel, since no prior art document describes an implantable structure for releasing an active ingredient, characterised in that lactic acid and/or a lactic acid oligomer is used as a plasticiser to reduce the transition temperature of the biodegradable polymer acting as a carrier for said structure. In



particular, D3 describes a plurality of plasticisers such as PEG or triacetin, but does not mention lactic acid as such. The same applies to D5.

The subject matter of claims 1-5 involves an inventive step:

D3 describes an implantable structure for the sustained and controlled release of an active ingredient. Said implantable structure contains

- (a) a lactic acid and glycolic acid copolymer
- (b) one or more plasticisers
- (c) an active ingredient (see column 3, line 37 to column 5, line 41).

D3 teaches that elasticity and processability can be improved by reducing the transition temperature via the addition of a plasticiser.

The problem that the present application is intended to solve is that of providing an alternative plasticiser.

The solution proposed by the present application resides in using lactic acid or a lactic acid oligomer as such as a plasticiser. Since no other prior art document mentions or suggests using a plasticiser having the same chemical entity as the PALAG copolymer, namely lactic acid or its oligomer as such, the proposed solution involves an inventive step. Moreover, the use of a plasticiser of this type results in an implantable structure with the same biocompatibility and tolerance properties as the PALAG copolymer.

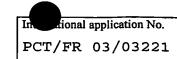
3b. The subject matter of claims 6-11 is novel, since no prior art document describes a method for making an implantable structure for the release of an active ingredient, characterised in that lactic acid and/or a lactic acid oligomer is used as a plasticiser and in that the compression moulding technique uses a preliminary transfer step carried out in a transfer chamber.

The subject matter of claims 6-11 involves an inventive step for the same reasons as those given in paragraph 3a above.

Moreover, D6, another document that could be seen as the closest prior art, describes a method for making implants that can be carried out by compression moulding (see pages 27-28), but said document does not provide any details concerning the production steps and, in particular, the use of a preliminary transfer step. Surprisingly, this step results in a uniform composite structure with coherent surfaces, which is non-porous and ensures the gradual and controlled release of the active ingredient (see also the current figures 13-15).

### For the regional phase:

- 4. Contrary to the requirements of PCT Rule 5.1(a)(ii), the description does not outline the relevant prior art set forth in documents D3, D5 and D6 and does not cite these documents.
- 5. The new claims filed are considered to be admissible. Consequently, the applicant is invited to make the text of the description consistent with that of these claims. In doing so, care should be



taken, particularly as far as the introductory part setting forth the problem or the advantages is concerned, to avoid extending the subject matter of the application beyond the content of the application as originally filed.

To facilitate examination of the compliance of the amended application documents with the provisions of PCT Article 34(2)(b), the applicant is invited to identify clearly the amendments made, whether they consist of additions, replacements or deletions, and to specify those passages of the application as filed on which said amendments are based (cf. also, PCT Rule 66.8(a)).

As the case may be, said amendments may be made by hand on a copy of the relevant parts of the application as filed.